REMARKS

Claims 1-22 are currently pending. New claims 23-25 have been added for consideration. Support for the new claims can be found in the specification as filed, particularly on page 9, paragraph numbers [0023], [0024] and [0025]. No issue of new matter is believed to be introduced by this amendment. If the new claims are entered, claims 1-25 will be under consideration.

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

Group I. Claims 1-10 drawn to a pharmaceutical composition.

Group II. Claims 11-22 drawn to a method of treating hepatic and immunological disorders.

Furthermore, the Examiner has noted that claim 1 is generic to a plurality of disclosed patentably distinct species and that Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, ie. *Actaea rubra, Anemone hepatica, Anemone nemorosa, Nigelle sativa or Ranunculus arvensis* or a specific combination thereof.

Responsive to the Requirement for Restriction, Applicants elect to prosecute the invention of Group I, which includes original claims 1-10, and would include new claims 23-25 if entered, drawn to a pharmaceutical composition, with traverse.

Applicants also elect by way of the requirement for election of species, *Nigella sativa*. All of the claims of the instant application read on the Markush group of claim 1, which includes this particular species. With respect to the election of Group I claims by way of the instant response to the requirement for restriction, Claims 1-10 and new claims 23-25 also read on this species.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as

disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define pharmaceutical compositions and methods of treating using said compositions, with properties so distinct as to warrant separate Examination and Search. Claims 1-10 are drawn to pharmaceutical compositions for treating hepatitis and immunological disorders, and are fundamentally related to Claims 11-22 of Group II, drawn to methods of treating hepatic disorders and immunological disorders using such compositions.

Applicants respectfully traverse the restriction for the following reasons. The Examiner alleges that the claims of Group I are the product, whereas the claims of Group II are the process. The claims of Group I are drawn to specific pharmaceutical compositions for treating hepatic disorders and immunological disorders. The claims of Group II are method of treatment claims using the compositions. Moreover, the methods of treating of Group II claims are fundamentally related to the claims of Group I, in that both sets of claims are drawn to compositions and methods of treating hepatic and immunological disorders. For example, the Examiner's attention is drawn in particular to claims 11-17, whereby the claims are drawn to methods of treating hepatic disorders or immunological disorders using the compositions of claim 1. Similarly, claim 1 reads on "pharmaceutical compositions for treating hepatitis or immunological disorders". Applicants respectfully assert that the search for any of the characteristics of the compositions separately classified by the Examiner as the invention of Group I would require an additional search of related subject matter in the claims of Group II, thus resulting in a duplicate search for similar material.

Applicants respectfully draw the Examiner's attention to the fact that the method of treating claims of Group II are dependent on the composition claims of Group I. Furthermore, the pharmaceutical composition claims of Group I specifically state

"pharmaceutical compositions for treating hepatitis and immunological disorders", and the method of treating claims, which also recite use of the compositions for hepatitis and immunological disorders, all depend from claim 1 or depend from intervening claims that depend from claim 1. Thus, a search on the claims of elected Group I , *eg.* pharmaceutical compositions for treating hepatitis and immunological disorders would require a search on related subject matter, since the claims of Group II read on methods of treating the same disorders using said compositions.

Furthermore, Applicants respectfully assert that a search and examination of elected Group I claims with Group II claims can be made without serious burden, and therefore the Examiner must examine all of the claims, or in the alternative, at least additional claims 11-17, of the Application on the merits.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the Claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include claims 11-17 with claims 1-10 and new claims 23-25 of elected Group I is in order.

However, if the restriction requirement is maintained, Applicants respectfully assert that if the product claims of Group I (claims 1-10 and 23-25), which have been elected by way of this response, are found to be allowable, the withdrawn process claims of Group II will be rejoined in accordance with the provisions of MPEP § 821.04, and will be fully examined for patentability in accordance with 37 CFR 1.104.

Furthermore, with respect to the election of species, the Examiner's attention is drawn to section 803.02 of the MPEP, whereby it notes that if no prior art is found that anticipates or renders obvious the elected species, the search of the Markush type claim will be extended to include the non-elected species.

A check in the amount of $75 is included herewith to cover the 3 new dependent claims. No other fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for Restriction is requested, and an early action on the merits of the claims is courteously solicited.

Respectfully submitted,

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